IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ASTRAZENECA UK LIMITED, IPR PHARMACEUTICALS, INC., and SHIONOGI SEIYAKU KABUSHIKI KAISHA, Plaintiffs, v. WATSON PHARMACEUTICALS, INC., WATSON PHARMA, INC., WATSON LABORATORIES, INC. (DE), WATSON LABORATORIES, INC. (NV), WATSON LABORATORIES, INC. (NY), WATSON LABORATORIES, INC. (CT), and WATSON LABORATORIES, INC. - FLORIDA Defendants.	)	C.A. No. 10-915-LPS

DEFENDANT WATSON LABORATORIES, INC. (NV)'S
ANSWER, DEFENSES AND COUNTERCLAIMS

Defendant Watson Laboratories, Inc. (NV) (hereinafter, "Watson Nevada" or "Defendant"), hereby answers the Complaint of Plaintiffs AstraZeneca UK Limited, IPR Pharmaceuticals, Inc. and Shionogi Seiyaku Kabushiki Kaisha ("Plaintiffs") as follows:

NATURE OF THE ACTION

1. Watson Nevada admits that the Complaint purports to state a civil action arising under 35 U.S.C. § 100 *et seq.* and under 35 U.S.C. § 271(e). Watson Nevada admits that the Complaint purports to relate to New Drug Application ("NDA") 202172 filed by Watson Nevada. Watson Nevada denies each and every remaining allegation contained in paragraph 1 of the Complaint.

PARTIES

2. Watson Nevada lacks sufficient information to form a belief as to the truth or falsity of the allegations contained in paragraph 2 of the Complaint, and therefore denies each and every allegation in paragraph 2 of the Complaint on that basis.

3. Watson Nevada lacks sufficient information to form a belief as to the truth or falsity of the allegations contained in paragraph 3 of the Complaint, and therefore denies each and every allegation in paragraph 3 of the Complaint on that basis.

4. Watson Nevada lacks sufficient information to form a belief as to the truth or falsity of the allegations contained in paragraph 4 of the Complaint, and therefore denies each and every allegation in paragraph 4 of the Complaint on that basis.

5. Pursuant to the Consent Order Pursuant To Fed. R. Civ. P. 41(a)(2) entered by the Court on December 23, 2010 dismissing the non-Watson Nevada entities ("the December 23, 2010 Consent Order"), the allegations in paragraph 5 are moot. Watson Nevada therefore provides no response to, or otherwise denies, those allegations on that basis.

6. Pursuant to the December 23, 2010 Consent Order, the allegations in paragraph 6 are moot. Watson Nevada therefore provides no response to, or otherwise denies, those allegations on that basis.

7. Pursuant to the December 23, 2010 Consent Order, the allegations in paragraph 7 are moot. Watson Nevada therefore provides no response to, or otherwise denies, those allegations on that basis.

8. Watson Nevada admits there is an entity named "Watson Laboratories, Inc." that is a Nevada corporation and has a principal place of business at 311 Bonnie Circle, Corona,

California 92880. Watson Nevada denies each and every remaining allegation contained in paragraph 8 of the Complaint.

9. Pursuant to the December 23, 2010 Consent Order, the allegations in paragraph 9 are moot. Watson Nevada therefore provides no response to, or otherwise denies, those allegations on that basis.

10. Pursuant to the December 23, 2010 Consent Order, the allegations in paragraph 10 are moot. Watson Nevada therefore provides no response to, or otherwise denies, those allegations on that basis.

11. Pursuant to the December 23, 2010 Consent Order, the allegations in paragraph 11 are moot. Watson Nevada therefore provides no response to, or otherwise denies, those allegations on that basis.

12. Pursuant to the December 23, 2010 Consent Order, the allegations in paragraph 12 are moot. Watson Nevada therefore provides no response to, or otherwise denies, those allegations on that basis.

13. Pursuant to the December 23, 2010 Consent Order, the allegations in paragraph 13 are moot. Watson Nevada therefore provides no response to, or otherwise denies, those allegations on that basis.

BACKGROUND

14. Watson Nevada lacks sufficient information to form a belief as to the truth or falsity of the allegations contained in paragraph 14 of the Complaint, and therefore denies each and every allegation in paragraph 14 of the Complaint on that basis.

15. Watson Nevada admits that Crestor® is a prescription drug that contains rosuvastatin calcium and is approved by the FDA for at least one indication. Watson Nevada

lacks sufficient information to form a belief as to the truth or falsity of the remaining allegations contained in paragraph 15 of the Complaint, and therefore denies each and every allegation in paragraph 15 of the Complaint on that basis.

16. Watson Nevada lacks sufficient information to form a belief as to the truth or falsity of the allegations contained in paragraph 16 of the Complaint, and therefore denies each and every allegation in paragraph 16 of the Complaint on that basis.

17. Watson Nevada admits the allegations contained in paragraph 17 of the Complaint.

18. Watson Nevada admits that a letter dated September 28, 2010 ("the Notice Letter") addressed to, *inter alia*, Jeff Pott of AstraZeneca Pharmaceuticals LP was on letterhead bearing Watson's logo at the top and the address of Watson Laboratories, Inc., 360 Mt. Kemble Avenue, Morristown, NJ 07960 at the bottom. Watson Nevada admits that the Notice Letter was signed by Krishna Joshi for Joyce DelGaudio, Executive Director of Regulatory Affairs for Watson Laboratories, Inc. Watson Nevada admits that written notice requesting access under the offer of confidential access included in the Notice Letter was to be addressed to Matthew O. Brady, Watson, 311 Bonnie Circle, Corona, CA 92880. Watson Nevada denies each and every remaining allegation contained in paragraph 18 of the Complaint.

19. Watson Nevada denies that on October 19 and 20, 1010, Plaintiffs asked Mr. Brady to identify which of the multiple subsidiaries of Watson Pharmaceuticals that are named Watson Laboratories, Inc. submitted NDA No. 202172 to the FDA. Watson Nevada lacks sufficient information to form a belief as to the truth or falsity of the remaining allegations contained in paragraph 19 of the Complaint and therefore denies each and every allegation in paragraph 19 of the Complaint on that basis.

20. Watson Nevada admits that Watson Nevada submitted NDA No. 202172 to the FDA for approval to engage in the commercial manufacture, use or sale of Watson Nevada's proposed rosuvastatin zinc tablets in strengths of 5 mg, 10 mg, 20 mg, and 40 mg. Watson Nevada admits that Watson Nevada's NDA contained or referred to the requisite data from safety or efficacy studies. Watson Nevada denies each and every remaining allegation contained in paragraph 20 of the Complaint.

JURISDICTION AND VENUE

21. Pursuant the Stipulation Regarding Dismissal jointly submitted by Plaintiffs and Defendant on December 17, 2010 ("the December 17, 2010 Stipulation Regarding Dismissal"), Watson Nevada agrees not to contest subject matter jurisdiction in the District of Delaware for this action. Watson Nevada denies any and all other allegations contained in paragraph 21 of the Complaint.

22. Pursuant to the December 23, 2010 Consent Order, the allegations in paragraph 22 pertaining to entities other than Watson Nevada are moot. Watson Nevada therefore provides no response to, or otherwise denies, the allegations regarding those entities on that basis. Pursuant the December 17, 2010 Stipulation Regarding Dismissal, Watson Nevada agrees not to contest venue, personal jurisdiction or subject matter jurisdiction in the District of Delaware for this action. Thus, the allegations contained in paragraph 22 of the Complaint are moot, and Watson Nevada therefore provides no response to, or otherwise denies, those allegations.

23. Pursuant to the December 23, 2010 Consent Order, the allegations in paragraph 23 pertaining to entities other than Watson Nevada are moot. Watson Nevada therefore provides no response to, or otherwise denies, the allegations regarding those entities on that basis. Pursuant the December 17, 2010 Stipulation Regarding Dismissal, Watson Nevada agrees not to

contest venue, personal jurisdiction or subject matter jurisdiction in the District of Delaware for this action. Thus, the allegations contained in paragraph 23 of the Complaint are moot, and Watson Nevada therefore provides no response to, or otherwise denies, those allegations.

24. Pursuant to the December 23, 2010 Consent Order, the allegations in paragraph 24 pertaining to entities other than Watson Nevada are moot. Watson Nevada therefore provides no response to, or otherwise denies, the allegations regarding those entities on that basis. Pursuant the December 17, 2010 Stipulation Regarding Dismissal, Watson Nevada agrees not to contest venue, personal jurisdiction or subject matter jurisdiction in the District of Delaware for this action. Thus, the allegations contained in paragraph 24 of the Complaint are moot, and Watson Nevada therefore provides no response to, or otherwise denies, those allegations.

25. Pursuant to the December 23, 2010 Consent Order, the allegations in paragraph 25 pertaining to entities other than Watson Nevada are moot. Watson Nevada therefore provides no response to, or otherwise denies, the allegations regarding those entities on that basis. Pursuant the December 17, 2010 Stipulation Regarding Dismissal, Watson Nevada agrees not to contest personal jurisdiction in the District of Delaware for this action. Thus, the allegations contained in paragraph 25 of the Complaint are moot, and Watson Nevada therefore provides no response to, or otherwise denies, those allegations.

26. Pursuant to the December 23, 2010 Consent Order, the allegations in paragraph 26 pertaining to entities other than Watson Nevada are moot. Watson Nevada therefore provides no response to, or otherwise denies, the allegations regarding those entities on that basis. Watson Nevada denies any and all other allegations contained in paragraph 26 of the Complaint.

27. Pursuant the December 17, 2010 Stipulation Regarding Dismissal, Watson Nevada agrees not to contest venue in the District of Delaware for this action. Watson Nevada denies any and all other allegations contained in paragraph 27 of the Complaint.

INFRINGEMENT OF
U.S. PATENT NO. RE 37,314 UNDER 35 U.S.C. § 271(e)(2)

28. Watson Nevada incorporates by reference paragraphs 1-27 of this Answer as if fully set forth herein.

29. Watson Nevada admits that United States Patent No. RE 37,314 ("the '314 patent") is entitled "Pyrimidine Derivatives," and lists a reissue date of August 7, 2001. Watson Nevada also admits that the attachment A of the Complaint purports to be a copy of the '314 patent. Watson Nevada denies that the '314 patent was duly and legally reissued. Watson Nevada lacks sufficient information to form a belief as to the truth or falsity of the remaining allegations contained in paragraph 29 of the Complaint, and therefore denies each and every remaining allegation in paragraph 29 of the Complaint on that basis.

30. Watson Nevada lacks sufficient information to form a belief as to the truth or falsity of the allegations contained in paragraph 30 of the Complaint, and therefore denies each and every allegation in paragraph 30 of the Complaint on that basis.

31. To the extent the allegations contained in paragraph 31 of the Complaint relate to entities other than Watson Nevada, those allegations are moot in view of the December 23, 2010 Consent Order. Watson Nevada therefore provides no response to, or otherwise denies, the allegations regarding those entities on that basis. Watson Nevada admits that Watson Nevada submitted NDA No. 202172 for rosuvastatin zinc tablets to the FDA in order to obtain approval to market those tablets in the United States before the expiration of the '314 patent. Watson Nevada admits that Watson Nevada certified, pursuant to 21 U.S.C. § 355(b)(2)(A)(iv), that,

inter alia, in Watson Nevada's opinion, and to the best of its knowledge, the '314 patent is invalid, unenforceable and/or will not be infringed by the commercial manufacture, use, or sale of Watson Nevada's rosuvastatin zinc tablets. Watson Nevada denies each and every remaining allegation contained in paragraph 31 of the Complaint.

32. To the extent the allegations contained in paragraph 32 of the Complaint relate to entities other than Watson Nevada, those allegations are moot in view of the December 23, 2010 Consent Order. Watson Nevada therefore provides no response to, or otherwise denies, the allegations regarding those entities on that basis. Watson Nevada admits that 35 U.S.C. § 271(e)(2)(A) states in part, "It shall be an act of infringement to submit (A) an application under section 505(j) of the Federal Food, Drug, and Cosmetic Act or described in section 505(b)(2) of such Act for a drug claimed in a patent or the use of which is claimed in a patent." Watson Nevada denies each and every remaining allegation in paragraph 32 of the Complaint.

33. To the extent the allegations contained in paragraph 33 of the Complaint relate to entities other than Watson Nevada, those allegations are moot in view of the December 23, 2010 Consent Order. Watson Nevada therefore provides no response to, or otherwise denies, the allegations regarding those entities on that basis. Watson Nevada denies each and every remaining allegation in paragraph 33 of the Complaint.

34. To the extent the allegations contained in paragraph 34 of the Complaint relate to entities other than Watson Nevada, those allegations are moot in view of the December 23, 2010 Consent Order. Watson Nevada therefore provides no response to, or otherwise denies, the allegations regarding those entities on that basis. Watson Nevada denies each and every remaining allegation in paragraph 34 of the Complaint.

35. To the extent the allegations contained in paragraph 35 of the Complaint relate to entities other than Watson Nevada, those allegations are moot in view of the December 23, 2010 Consent Order. Watson Nevada therefore provides no response to, or otherwise denies, the allegations regarding those entities on that basis. Watson Nevada denies each and every remaining allegation in paragraph 35 of the Complaint.

36. To the extent the allegations contained in paragraph 36 of the Complaint relate to entities other than Watson Nevada, those allegations are moot in view of the December 23, 2010 Consent Order. Watson Nevada therefore provides no response to, or otherwise denies, the allegations regarding those entities on that basis. Watson Nevada denies each and every remaining allegation in paragraph 36 of the Complaint.

PRAYER FOR RELIEF

Watson Nevada denies that Plaintiffs are entitled to the relief requested in paragraphs (1) – (7) of the Complaint.

DEFENSES

Watson Nevada sets forth the following defenses. Watson Nevada does not intend hereby to assume the burden of proof with respect to those matters that, under law, Plaintiffs bear the burden of proof.

First Defense — Non-Infringement

37. Watson Nevada does not infringe, induce infringement of, and/or contribute to the infringement of, any valid and/or enforceable claim of the '314 patent.

Second Defense — Invalidity of the '314 patent

38. One or more claims of the '314 patent are invalid for failure to satisfy the provisions of one or more of Sections 103 and/or 251 of Title 35 of the United States Code.

Third Defense — Improper Reissue of the '314 patent

39. The '314 patent was improperly reissued for failure to qualify as a correctable error under 35 U.S.C. § 251.

Fourth Defense — Unenforceability of the '314 patent

40. The '314 patent is unenforceable due to the failure of two Shionogi Seiyaku Kabushiki Kaisha ("Shionogi") patent department personnel to disclose material information to the United States Patent and Trademark Office ("PTO").

41. On June 12, 1992, Shionogi filed United States Patent Application Serial No. 07/897,793 ("the '793 application"). This application issued as United States Patent No. 5,260,440 ("the '440 patent") on November 9, 1993.

42. On August 27, 1998, Shionogi filed U.S. Patent Application Serial No. 09/141,731 ("the '731 application") seeking reissue of the '440 patent. This application issued as the '314 patent on August 7, 2001.

43. During the filing and prosecution of the '793 application, Shionogi patent department employees Ms. Tomoko Kitamura and Mr. Takashi Shibata each violated their duty of candor by withholding material prior art from the PTO in connection with the '793 application.

44. Ms. Kitamura and Mr. Shibata each withheld one or more of the following material prior art references:

(a) European Patent Application Publication No. 0367895 and its foreign

counterpart patent applications and publications, such as PCT Publication No. WO 90/03973 (collectively, "the Sandoz reference");

(b) The Search Reports from the European Patent Office relating to European Patent Application No. 92111090.4 ("the EP '90.4 application") that identified the Sandoz reference as "particularly relevant if taken alone"; and

(c) Japanese Published Patent Application No. 1989-261377 and its foreign counterpart patent applications and publications, such as European Patent Application Publication No. 0330057 (collectively, "the Bayer reference").

The Sandoz Reference and European Search Report

45. The Sandoz reference was published on May 16, 1990, and is prior art to the '314 patent under 35 U.S.C. § 102(b). The Sandoz reference discloses a statin drug that renders obvious at least Claim 1 of the '793 application and the '440 patent.

46. Example 1(b) of the Sandoz reference discloses a statin compound that differs from rosuvastatin only in that it has a dimethylamino substitution at the 2-position on the pyrimidine ring, while rosuvastatin has a N-methyl, N-methylsulfonyl substitution at that position.

47. Rosuvastatin was known as "S-4522" at Shionogi during the time it was being developed.

48. The Sandoz reference discloses that the compound of Example 1(b) is a particularly preferred compound.

49. Before the issuance of the '440 patent, Mr. Shibata was substantively involved in the filing and prosecution of the '793 application, and knew of the Sandoz reference and its

materiality to the '793 application, but intentionally withheld the Sandoz reference from the PTO with intent to deceive.

50. On or around October 16, 1992, Mr. Shibata received from Shionogi's European patent attorneys the European Search Report made in connection with the EP '90.4 application. The European Search Report identified the Sandoz reference as an "X" reference, which means that the Sandoz reference was "particularly relevant if taken alone." As filed, claim 1 of the EP '90.4 application was identical to original claim 1 of the '793 application.

51. On or about January 21, 1993, Mr. Shibata informed Masatake Yasumi, the head of Shionogi's patent department at that time, that Mr. Shibata had requested a comparative study between S-4522 and three prior art compounds, one of which was compound 1(b) of the Sandoz reference. The comparative study was requested to support Shionogi's pending patent applications relating to S-4522. Mr. Shibata was involved in choosing these specific compounds.

52. On August 27, 1998, Shionogi filed an application for the reissue of the '440 patent in view of the Sandoz reference. Specifically, in support of that reissue application, Shionogi submitted a declaration to the PTO stating that the "Patentee claimed more than he had a right to claim by reason of the disclosure of European Patent Application 0 367 895, published May 16, 1990." Shionogi then amended two of the issued claims of the '440 patent, cancelled two of the issued claims of the '440 patent, and added three claims.

53. Shionogi's reissue declaration, its amendment and cancellation of issued claims, and Shionogi's comparative testing of the Sandoz compound against the S-4522 compound confirm that the Sandoz reference was highly material prior art to the '793 application. The Sandoz reference, furthermore, was not cumulative of any prior art disclosed during prosecution of the '793 application.

54. Mr. Shibata's withholding of the Sandoz reference from the PTO during the prosecution of the '793 application with intent to deceive constitutes inequitable conduct and renders the '314 patent unenforceable.

55. The European Search Report was highly material to the '793 application for all the reasons associated with the Sandoz reference, and because it specifically indicated the high relevance of the Sandoz reference to the claims in the '793 application. The European Search Report, furthermore, was not cumulative of any prior art reference disclosed during prosecution of the '793 application.

56. Mr. Shibata knew of the European Search Report and its materiality before the issuance of the '440 patent.

57. Mr. Shibata's withholding of the European Search Report from the PTO during the prosecution of the '440 patent with intent to deceive constitutes inequitable conduct and renders the '314 patent unenforceable.

The Bayer Reference

58. The Bayer reference was published in 1989 and constitutes prior art to the '440 patent under 35 U.S.C. § 102(b).

59. The Bayer reference claims a group of compounds that includes rosuvastatin calcium, one of the preferred embodiments of the '440 patent, and discloses a genus of compounds that overlaps with the broad genus claims, including Claim 1, of the '440 patent.

60. The Bayer reference is material to the '793 application because it renders obvious at least one claim in the '793 application. The Bayer reference, furthermore, was not cumulative of any prior art reference disclosed during prosecution of the '793 application.

61. Ms. Kitamura was responsible for drafting the application for the '440 patent and the corresponding patent applications in other foreign jurisdictions, such as Japan and Europe. Ms. Kitamura first filed Japanese Patent application number 3-188015 ("the JP '015 application"). Then, in June 1992, Ms. Kitamura filed the corresponding United States and European applications, the '793 application and the EP '90.4 application, respectively.

62. At least as early as June 10, 1991, Ms. Kitamura and Mr. Shibata received a Shionogi search report that identified the Bayer reference as a prior art reference that encompassed at least four of the seven compounds sought to be claimed in the '793 application.

63. On November 15, 1991, Ms. Kitamura was listed as a recipient on a memorandum again identifying the Bayer reference as relevant prior art to S-4522, and concluding that the Bayer reference literally encompassed S-4522. That memorandum warned that nothing regarding the development of S-4522 should be leaked outside of Shionogi. This recommendation was based on Shionogi's concern that if Bayer became aware of S-4522, they would narrow the patent claims in the Bayer reference to focus on the S-4522 compound.

64. The fact that S-4522 was covered by the claims of the Bayer reference was again reported in a December 4, 1991 memorandum sent to Mr. Shibata. The memorandum also discussed whether Shionogi should consider suspending work on S-4522 in light of the Bayer reference. The memorandum alternatively noted that, under Japanese patent law, the Bayer application would be considered withdrawn after a seven year period (ending February 1996) if no request for examination was made. The memorandum concluded that, if the Bayer application became an issued patent, it would be necessary to negotiate a patent license with Bayer, and reiterated the importance of maintaining the secrecy of S-4522.

65. On July 20, 1992, Mr. Yasumi, the head of Shionogi's patent department at that time, authored a memorandum regarding the status of Shionogi's patents covering S-4522. That memorandum stated that the JP '015 application, which covered S-4522, would likely be rejected in Japan because it was identical to the invention disclosed in the Bayer reference.

66. The JP '015 application was the Japanese counterpart to the '793 application.

67. In that memorandum, Mr. Yasumi stated that comparative testing between S-4522 and compounds disclosed in the Bayer reference was necessary to obtain the patents covering S-4522.

68. On or about January 21, 1993, Mr. Shibata informed Mr. Yasumi that he had requested a comparative study between S-4522 and three prior art compounds, one of which was a compound disclosed in the Bayer reference.

69. In an office action mailed February 2, 1999, the PTO rejected all original claims from the '440 patent that were pending in the '731 reissue application over the Bayer reference. Shionogi subsequently cancelled all remaining claims that were originally issued in the '440 patent.

70. Shionogi's internal memoranda warning about the Bayer reference, the rejection of the original '440 patent claims pending in the '731 reissue application over the Bayer reference, their subsequent cancellation by Shionogi, and Shionogi's comparative testing of the Bayer reference compound against the S-4522 compound all confirm that the Bayer reference was highly material prior art to the '793 application. The Bayer reference, furthermore, was not cumulative of any prior art disclosed during prosecution of the '793 application.

71. Ms. Kitamura and Mr. Shibata, who were both substantively involved in the prosecution of the '793 application, knew of the Bayer reference and its materiality to the '793 application prior to the issuance of the '440 patent.

72. Despite knowing of the Bayer reference and its materiality to the '793 application, Ms. Kitamura and Mr. Shibata violated their duty of candor by withholding the Bayer reference from the PTO with intent to deceive.

73. Ms. Kitamura's and Mr. Shibata's withholding of the Bayer reference from the PTO during the prosecution of the '440 patent with intent to deceive constitutes inequitable conduct and renders the '314 patent unenforceable.

COUNTERCLAIMS

Defendant/Counterclaimant Watson Laboratories, Inc. (NV) ("Watson Nevada") hereby asserts Counterclaims against Plaintiffs/Counterdefendants AstraZeneca UK Limited, IPR Pharmaceuticals, Inc. and Shionogi Seiyaku Kabushiki Kaisha ("Counterdefendants") as follows:

PARTIES

1. Counterclaimant Watson Nevada is a corporation organized and existing under the laws of the State of Nevada, having a principal place of business at 311 Bonnie Circle, Corona, California 92880.

2. According to the Complaint, Counterdefendant AstraZeneca UK Limited ("AstraZeneca") is a corporation operating and existing under the laws of the United Kingdom, with its principal place of business at 2 Kingdom Street, London, W2 6BD, England.

3. According to the Complaint, Counterdefendant IPR Pharmaceuticals, Inc. ("IPR") is a corporation operating and existing under the laws of Puerto Rico, with its principal place of business at Carr 188 Lote 17, San Isidro Industrial Park, Canovanas, Puerto Rico 00729.

4. According to the Complaint, Counterdefendant Shionogi Seiyaku Kabushiki Kaisha ("Shionogi") is a corporation operating and existing under the laws of Japan, with its principal place of business at 1-8, Doshomachi 3-chome, Chuo-ku, Osaka 541-0045 Japan.

JURISDICTION AND VENUE

5. This is an action for declaratory judgment that the '314 patent and U.S. Patent No. 6,316,460 ("the '460 patent") are not infringed by the rosuvastatin zinc products described in Watson Nevada's NDA No. 202172. A true and correct copy of the '460 patent is attached hereto as Exhibit A.

6. The declaratory judgment aspects of this action are based on an actual controversy between the parties concerning the non-infringement of the patents-in-suit, Watson Nevada's right to continue to seek approval of NDA No. 202172, and upon approval by the FDA, to manufacture, import, use, sell and/or offer to sell its rosuvastatin zinc NDA products in the United States.

7. This Court has subject matter jurisdiction pursuant to, *inter alia*, 28 U.S.C. §§ 1331, 1338(a), 2201, 2202, and 35 U.S.C. § 271(e)(5).

8. This Court has personal jurisdiction over AstraZeneca on the basis of, *inter alia*, its contacts with the District of Delaware relating to the subject matter of this action, including having filed this suit.

9. This Court has personal jurisdiction over IPR on the basis of, *inter alia*, its contacts with the District of Delaware relating to the subject matter of this action, including having filed this suit.

10. This Court has personal jurisdiction over Shionogi on the basis of, *inter alia*, its contacts with the District of Delaware relating to the subject matter of this action, including having filed this suit.

11. Venue is proper in this Court pursuant to 28 U.S.C. §§ 1391 and 1400(b), and by Counterdefendants' choice of forum.

BACKGROUND

12. Watson Nevada has submitted, and is continuing to seek FDA approval of, NDA No. 202172 directed towards rosuvastatin zinc compositions. Watson Nevada's NDA seeks approval for Watson Nevada to engage in the commercial manufacture, use and sale of rosuvastatin zinc compositions, which Counterdefendants allege infringe the '314 patent.

13. On information and belief, Shionogi is the assignee of the '314 patent.

14. On information and belief, IPR and AstraZeneca hold all substantial rights in the '314 and '460 patents, including the right to sue for infringement thereof.

15. One or more Counterdefendants caused the '314 and '460 patents to be listed in FDA's Approved Drug Products with Therapeutic Equivalence Evaluations ("the Orange Book") for the drug CRESTOR®.

16. According to the Complaint, IPR is the holder of NDA No. 021366 for CRESTOR® Tablets containing the active ingredient rosuvastatin calcium.

17. As a consequence of listing the '314 and '460 patents in the Orange Book, Counterdefendants were and are representing that the '314 and '460 patents claim CRESTOR® and rosuvastatin calcium, and that patent infringement actions relating to the '314 and '460 patents could reasonably be expected to be brought against unlicensed filers of NDA's for which patent certification would be required.

18. On information and belief, Counterdefendants have enforced and continue to vigorously enforce their alleged intellectual property rights by filing patent infringement actions, including the infringement action alleged in the Complaint.

19. Watson Nevada submitted NDA No. 202172 to the FDA.

20. Watson Nevada certified to the FDA in its NDA No. 202172 that its proposed rosuvastatin zinc product will not infringe any valid and enforceable claim of the '314 and '460 patents.

21. Watson Nevada notified Counterdefendants of the factual and legal bases for Watson Nevada's certification with respect to the '314 and '460 patents in its September 28, 2010 Notice Letter.

22. The Notice Letter included an offer of confidential access pursuant to 21 U.S.C. § 355(c)(3)(D)(i)(III).

23. By submitting certification regarding the '314 and '460 patents in its NDA No. 202172, and by notifying Counterdefendants of the same, Watson Nevada has created a case or controversy under Article III of the Constitution regarding the infringement, validity and/or unenforceability of the '314 and '460 patents.

24. This case or controversy provided subject matter for Counterdefendants to bring and maintain a suit alleging infringement of the '314 patent.

25. It has been more than 45 days since Counterdefendants received Watson's September 28, 2010 Notice letter. Counterdefendants have not alleged infringement of the '460 patent.

26. Counterdefendants have sued Watson Nevada for infringement of the '314 patent, and have not provided a covenant not to sue for alleged infringement of the '460 patent.

27. There is an actual, substantial and continuing justiciable case and controversy between Watson Nevada and Counterdefendants regarding the infringement, invalidity and/or unenforceability of the '314 and '460 patents over which this Court can and should exercise jurisdiction and declare the rights of the parties.

FIRST COUNTERCLAIM —
DECLARATORY JUDGMENT OF NONINFRINGMENT OF THE '314 PATENT

28. Watson Nevada repeats and realleges paragraphs 1-27 of its Counterclaims as if set forth specifically herein.

29. Watson Nevada does not infringe any claim of the '314 patent, either directly, indirectly, or under the doctrine of equivalents.

30. The sale, offer for sale, manufacture, importation or use of Watson Nevada's rosuvastatin zinc NDA products will not constitute infringement of any claim of the '314 patent, either directly, indirectly, or under the doctrine of equivalents.

SECOND COUNTERCLAIM —
DECLARATORY JUDGMENT OF INVALIDITY OF THE '314 PATENT

31. Watson Nevada repeats and realleges paragraphs 1-30 of its Counterclaims as if set forth specifically herein.

32. One or more claims of the '314 patent are invalid for failure to comply with one or more of the conditions for patentability set forth in 35 U.S.C. §§ 103 and/or 251.

THIRD COUNTERCLAIM —
DECLARATORY JUDGMENT OF IMPROPER REISSUE OF THE '314 PATENT

33. Watson Nevada repeats and realleges paragraphs 1-32 of its Counterclaims as if set forth specifically herein.

34. The '314 patent was improperly reissued for failure to qualify as a correctable error under 35 U.S.C. § 251.

FOURTH COUNTERCLAIM —
DECLARATORY JUDGMENT OF UNENFORCEABILBILTY OF THE '314 PATENT

35. Watson Nevada repeats and realleges paragraphs 1-34 of its Counterclaims as if set forth specifically herein.

36. Watson Nevada repeats and realleges paragraphs 40-73 of its Fourth Affirmative Defense as if set forth specifically herein.

37. Watson Nevada is entitled to a judicial declaration that the '314 patent is unenforceable due to inequitable conduct.

FIFTH COUNTERCLAIM —
DECLARATORY JUDGMENT OF NONINFRINGMENT OR INVALIDITY OF THE '460 PATENT

38. Watson Nevada repeats and realleges paragraphs 1-37 of its Counterclaims as if set forth specifically herein.

39. Watson Nevada does not infringe any valid claim of the '460 patent, either directly, indirectly or under the doctrine of equivalents.

40. The sale, offer for sale, manufacture, importation or use of Watson Nevada's rosuvastatin zinc NDA products would not constitute infringement of any claim of the '460 patent either directly, indirectly or under the doctrine of equivalents.

41. If any claim of the '460 patent is expanded under the doctrine of equivalents to include Watson Nevada's rosuvastatin zinc NDA products, Watson Nevada is entitled to a judicial declaration that any such claim is invalid under 35 U.S.C. § 103.

DEMAND FOR JUDGMENT

WHEREFORE, Watson Nevada prays for the following relief:

A. That all claims against Watson Nevada be dismissed with prejudice and that all relief requested by Plaintiffs/Counterdefendants be denied;

B. That a judgment be entered declaring that Watson Nevada has not, and does not, infringe directly, indirectly, or under the doctrine of equivalents, any valid and enforceable claim of United States Patent Nos. RE 37,314 and 6,316,460, that Watson Nevada has a lawful right to obtain FDA approval of NDA No. 202172, and further that Watson Nevada has a lawful right to manufacture, import, use, sell and/or offer to sell its rosuvastatin zinc NDA products in the United States once approved by the FDA;

C. That a judgment be entered declaring that the claims of the '314 patent and the '460 patent are invalid for failure to comply with one or more of the requirements of 35 U.S.C. §§ 103 and/or 251;

D. That a judgment be entered that the '314 patent was improperly reissued for failure to qualify as correctable error under 35 U.S.C. § 251;

E. That a judgment be entered that the claims of the '314 patent are unenforceable due to inequitable conduct before the United States Patent and Trademark Office;

F. That Plaintiffs/Counterdefendants, their parents and/or subsidiaries, and their agents, representatives, attorneys and those persons in active concert or participation with them who receive actual notice thereof, be preliminarily and permanently enjoined from threatening or initiating infringement litigation against Watson Nevada or any of its customers, dealers or suppliers, or any prospective or present sellers, dealers, distributors or customers of Watson Nevada, or charging any of them either orally or in writing with infringement of the '314 and/or '460 patents;

G. That a judgment be entered declaring that this action is an exceptional case within the meaning of 35 U.S.C. § 285, and that Watson Nevada is entitled to recover its reasonable attorneys' fees upon prevailing in this action;

H. That Watson Nevada be awarded costs, attorneys fees and other relief, both legal and equitable, to which they may be justly entitled; and

I. That Watson Nevada be awarded such other and further relief as is just and proper.

POTTER ANDERSON & CORROON LLP

By: */s/ Richard L. Horwitz*
Richard L. Horwitz (#2246)
David E. Moore (#3983)
Hercules Plaza, 6th Floor
1313 North Market Street
P. O. Box 951
Wilmington, DE 19899
(302) 984-6000
rhorwitz@potteranderson.com
dmoore@potteranderson.com

Attorneys for Defendants
Watson Laboratories, Inc. (NV)

OF COUNSEL:

Steven A. Maddox
KNOBBE, MARTENS, OLSON & BEAR, LLP
1717 Pennsylvania Avenue, NW, Suite 900
Washington, DC 20006
Tel: (202) 640-6400
steve.maddox@kmob.com

Payson LeMeilleur
KNOBBE, MARTENS, OLSON & BEAR, LLP
2040 Main Street, 14th Floor
Irvine, CA 92614
Tel: (949) 760-0404
plemeilleur@kmob.com

Dated: December 30, 2010
995178 / 36235

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

CERTIFICATE OF SERVICE

I, Richard L. Horwitz, hereby certify that on December 30, 2010, the attached document was electronically filed with the Clerk of the Court using CM/ECF which will send notification to the registered attorney(s) of record that the document has been filed and is available for viewing and downloading.

I hereby certify that on December 30, 2010, the attached document was electronically mailed to the following person(s)

Mary W. Bourke
Connolly Bove Lodge & Hutz LLP
1007 N. Orange Street
Wilmington, DE 19899
mbourke@cblh.com

Henry J. Renk
Fitzpatrick, Cella, Harper & Scinto
1290 Avenue of the Americas
New York, NY 10104-3800
hrenk@fchs.com

Kenneth M. Frankel
York Moody Faulkner
Charles E. Lipsey
Ford Farabow
Mary K. Ferguson, Ph.D.
Finnegan, Henderson, Farabow, Garrett & Dunner LLP
11955 Freedom Drive, Suite 800
Reston, VA 20190
Kenneth.frankel@finnegan.com
York.faulkner@finnegan.com
Charles.lipsey@finnegan.com
Ford.farabow@finnegan.com
Mary.ferguson@finnegan.com

By: */s/ Richard L. Horwitz*
Richard L. Horwitz
David E. Moore
Hercules Plaza, 6th Floor
1313 N. Market Street
Wilmington, Delaware 19899-0951
(302) 984-6000
rhorwitz@potteranderson.com
dmoore@potteranderson.com

995181 / 36235